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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/689,778	10/21/2003	Jaymin C. Shah	PC25071A	4530

23913 7590 12/08/2006

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NEW YORK, NY 10017-5612

EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 12/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/689,778

Applicant(s)

SHAH, JAYMIN C.

Examiner

James W. Rogers, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 6,232,304 B1, cited by applicants) in view of Greengard et al. (US2003/0109419) and in view of Yuan et al. (US 5,594,141).

Kim discloses inclusion complexes of aryl-heterocyclic salts (including ziprasidone mesylate) and cyclodextrins (including SBECD), the amounts of the aryl-heterocyclic salt and cyclodextrins are within applicants claimed range. See abstract, col 6 lin 48-col 7 lin 13 and examples. Regarding claims 11 and 15 the limitation that the kit contains a ziprasidone in a first package and a second package containing an aqueous solution are considered met by the examiner because the Kim patent discloses that the inclusion complex can be formed in-situ adding the ziprasidone salt directly to a solution of cyclodextrins dissolved in water, therefore it would have been obvious to the skilled artisan that a package could contain the ziprasidone salt and aqueous solutions separately and then reconstituted. See col 7 lin 48-col 8 lin 9. Alternatively the inclusion complex containing ziprasidone can be dried and stored at room temperature for a period of up to two years and reconstituted with an aqueous solution into a product solution as needed, while in this embodiment the dry matter includes the ziprasidone

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and cyclodextrin, it is the examiners opinion that it would still be obvious to the skilled artisan that the aqueous solution could contain the cyclodextrin and the solid would comprise only the ziprasidone, since from the previous formulation of the complex the cyclodextrin was in the aqueous layer and the inclusion complex was formed in-situ by simply mixing the dry ziprasidone and the aqueous solution. Therefore the disclosure of Kim could obviously lead one skilled in the art to the same two package kit as applicants currently claimed invention, wherein the first package contained the dry ziprasidone and the second package contained an aqueous layer including cyclodextrin in which at the time the composition was needed it could be reconstituted for intramuscular injection.

Kim is silent on the use of the two excipients NaCMC and polyoxyethylene sorbitan ester in the composition.

Greengard is used primarily for the disclosure within that pharmaceutical compositions comprising anti-psychotic drugs (including the disclosed actives in combination with ziprasidone) which are formulated for injection can comprise a surfactant such as Tween 80 e.g. polysorbate 80. [353], [397] and [0410].

Yuan is used primarily for the disclosure within that atypical anti-psychotic aryl-heterocycles were already known in the art to be used in aqueous suspensions containing excipients such as suspending agents including NaCMC for intramuscular injection. See col 2 lin 21-27, col 10 lin 22-33 and col 11 lin 4-8. While neither the Greengard or Yuan references disclose the exact amounts of polysorbate or NaCMC as claimed in claims 12 and 15 it is the examiners stance that generally, differences in concentration or temperature will not support the patentability of subject matter

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encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."); *In re Hoeschele*, 406 F.2d 1403, 160 USPQ 809 (CCPA 1969).

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the composition disclosed in Kim and adding the excipients disclosed within Greengard and Yuan. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of injectable aqueous compositions containing an atypical anti-psychotic. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. *In re Kerhoven*, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al. (US 6,232,304 B1, cited by applicants) in view of Francois et al. (US 2003/0157180).

Kim is disclosed above. Kim is silent on the use of the two excipients NaCMC and polyoxyethylene sorbitan ester in the composition.

Francois is used primarily to show that the use of NaCMC and polysorbate e.g. Tweens in injectable compositions containing atypical anti-psychotic aryl-heterocycles (micronized risperidone) was already well known in the art. See abstract, [0023],[0029]-[0035], [0043],[0049]-[0054] and composition examples. Regarding claims 12 and 15 the limitations that the weight percent of NaCMC and the polyoxyethylene sorbitan ester are met because Francois discloses that the composition comprises 0.5 to 3% of a wetting agent (polysorbate) and 0.5 to 2% of a suspending agent (NaCMC). Also disclosed in the examples is a composition containing 1.1% polysorbate (satisfies about 1% w/v) and 1% NaCMC.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the composition disclosed in Kim and adding the excipients disclosed within Francois. It is generally considered to be prime facie obvious to combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of

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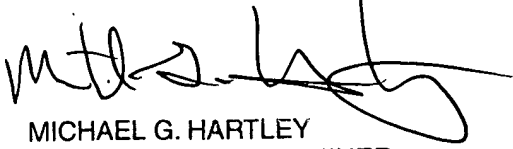
conventional components of injectable aqueous compositions containing an atypical anti-psychotic. It therefore follows that the instant claims define prime facie obvious subject matter. Cf. In re Kerhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980).

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER